UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY PATENT LITIGATION	MDL No. 1592 (MLW) This Document Relates to All Actions

PLAINTIFF GENENTECH INC.'S OPPOSITION TO COLUMBIA UNIVERSITY'S MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

Dated: September 22, 2004

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Preliminary Statement

The pending Emergency Motion To Dismiss for Lack of Subject Matter Jurisdiction[1] is nothing more than another attempt by The Trustees of Columbia University in the City of New York ("Columbia") to postpone a determination as to the enforceability of United States Patent Number 6,455,275 (the "'275 Patent"). Columbia's motion is without merit.

Columbia's motion is based on its Covenant Not To Sue filed on September 1, 2004 (the "Covenant"). The Covenant, however, is insufficient to divest this Court of subject matter jurisdiction over any part of the dispute before it. Rather than resolving the controversy that led Genentech to file its declaratory judgment claims, the Covenant leaves Genentech vulnerable to a potential infringement suit by Columbia immediately upon the dismissal of this action, or at any later date that Columbia deems more convenient. As a result, granting Columbia's motion would mean that the invalid '275 Patent will remain in force and uncertainty will persist regarding Genentech's products and, indeed, an entire segment of its business. Resolving such uncertainty, however, is one of the primary – and proper – purposes of Genentech's declaratory judgment claims. Accordingly, the controversy between Genentech and Columbia should proceed as currently scheduled.

[1] Columbia's Memorandum in Support of Emergency Motion To Dismiss for Lack of Subject Matter Jurisdiction, filed on September 2, 2004, is cited herein as "Mem. at __."

Statement of Facts

The Technology at Issue and the '275 Patent

The technology at issue in this case[2] is recombinant DNA technology, particularly technology relating to the introduction of DNA into cells for the purpose of producing proteinaceous materials. In general, the '275 Patent discloses introduction of a gene of interest and a "selectable marker" gene into a cell. The gene of interest provides instructions for the cell to produce a desired protein while the selectable marker gene allows identification of those cells that have taken up the DNA ("cotransformed cells"). Typically, in the biotechnology industry, after the DNA is introduced, those cells that have been successfully cotransformed are selected and cultured to create additional identical cells. Sometimes, the gene of interest and selectable marker gene are "amplified" – a process by which the number of copies of the gene of interest in the cotransformed cell are increased, with a commensurate increase in the cell's ability to produce the protein corresponding to that gene.

The '275 Patent generally claims cotransformed cells, constructs of DNA to be used for cotransforming a cell, and methods of transforming a cell. Biotechnology companies such as Genentech generally do not sell cotransformed cells or DNA constructs. Instead, they use the cotransformed cells and DNA constructs to produce proteins that become the active components of pharmaceutical products. The time that generally elapses between the cotransformation of a cell and the sale of a product created from the proteins produced by the cell – during which time the research, development,

[2] This abbreviated discussion is provided to illustrate the general nature of the processes at issue in this case.

clinical testing, and preparation for market of the protential drug compound must be completed – is on the order of years.

Columbia obtained its first patent on this technology – United States Patent Number 4,399,216 (the "'216 Patent") – over twenty years ago, in August of 1983. After the '216 Patent issued, Columbia and Genentech entered into an October 12, 1987 license agreement (the "License Agreement"), under which Genentech agreed to pay royalties and other fees in exchange for a non-exclusive license to the '216 Patent and certain related patents. Genentech paid more than $70 million to Columbia under the License Agreement.

The '275 Patent issued on September 24, 2002, twenty-two years after the application for the '216 Patent had been filed and two years after the '216 Patent had expired. Although the '275 Patent and the expired '216 Patent cover the same technology, Columbia demanded that Genentech pay additional royalties related to the '275 Patent. As a result, Genentech made royalty payments of more than $100,000 for use of the technology claimed in the '275 Patent. Genentech subsequently stopped paying royalties related to the '275 Patent.

By a notice dated March 18, 2004, Columbia breached the License Agreement by unilaterally terminating the license based on alleged breaches by Genentech, including "(1) failing to pay all royalties due on licensed products manufactured on or after September 24, 2002, the date on which the '275 was issued; (2) failing to provide required reports for all such unpaid royalties; . . . and (5) failing to pay all fees due under

the license agreement." (Smith Decl. Ex. A (March 18, 2004 Letter from Michael J. Cleare).)[3]

Columbia's Efforts To Delay a Judicial Determination of the Invalidity and Unenforceability of the '275 Patent

On April 11, 2003, only a few months after Columbia demanded royalties related to the '275 Patent, Genentech filed suit against Columbia, alleging that the '275 Patent is invalid and unenforceable. In the following months, the other parties to this multidistrict litigation also filed complaints seeking a declaration of invalidity. Columbia's response from the start was to engage in a campaign of delay to avoid a judicial determination of the invalidity and unenforceability of the '275 Patent.[4]

If the multiple lawsuits were not sufficient to alert Columbia to the infirmities of the '275 Patent, the Public Patent Foundation filed a request for reexamination of the '275 Patent on February 25, 2004. That request was granted by the United States Patent and Trademark Office on May 6, 2004. Columbia then sought – three months after the request for reexamination – a stay of this multidistrict litigation. Then, more than a year after Genentech's initial complaint, Columbia filed a reissue application related to the '275 Patent and argued that the reissue application justified a stay. Columbia failed, however, to persuade the Court that attempts to resolve the validity of the '275 Patent

[3] On September 13, 2004, Columbia purported to withdraw this notice, except with respect to Genentech's failure to allow an audit of its books and records in accordance with the terms of the License Agreement. Thus, Columbia continues to claim that it has terminated the License Agreement but attempts to claim retroactively that the termination – which occurred nearly six months earlier – is unrelated to the '275 Patent. (Joint Report (Doc. No. 98), Ex. B (September 13, 2004 Letter from David I. Gindler).)

[4] For a detailed discussion of Columbia's delay tactics, see June 16, 2004 Joint Opposition to Columbia's Motion To Stay Litigation Pending Conclusion of Reexamination and Reissue Proceedings in the Patent and Trademark (Doc. No. 32), at 4-8.

should be forestalled any longer. See August 16, 2004 Memorandum and Order (Doc. No. 79). The Court imposed a schedule that would permit a prompt determination of invalidity due to double patenting. See id. at 11-12. Faced with an impending judicial determination of the '275 Patent's invalidity and unenforceability, Columbia has made a last ditch effort to derail the process and maintain the '275 Patent's viability by filing its Covenant.

Columbia's September 1, 2004 Covenant

In its Covenant, Columbia promises:

> not to assert any claim of patent infringement against Genentech, Inc. . . . under . . . the '275 Patent as it presently reads, with respect to any product currently made, used, offered for sale, sold, or imported by plaintiffs, or any product that was made, used, offered for sale, sold, or imported by plaintiffs prior to the date of this Covenant. (Cov. at 1.)

Columbia has clarified that this covenant does not apply to (1) DNA constructs or cotransformed cells created by Genentech for the first time after September 1, 2004, unless the protein encoded by the DNA construct or cotransformed cell was sold by Genentech on or before September 1, 2004; (2) methods of using such DNA constructs or cotransformed cells; and (3) proteins produced using such DNA constructs or cotransformed cells. (Joint Report (Doc. No. 98), Ex. A (September 17, 2004 Letter from David I. Gindler) ¶¶ 4(a)-4(c).) Columbia's explicit exclusions from the Covenant render it insufficient to eliminate the case and controversy between Genentech and Columbia.[5]

[5] Columbia's motive merely to delay rather than to eliminate the controversy here is evidenced in part by Columbia's position that the Covenant does not extend to patent claims that may result from the '159 patent application and that are identical or substantially similar to claims in the '275 Patent. (Joint Report (Doc. No. 98), Ex. A (September 10, 2004 Letter from David I. Gindler) ¶ 4 ("The Covenant does not apply to any claim in any patent that may issue in the future based upon the pending '159 application, irrespective of whether plaintiffs contend that such claim is the same as, or

Argument

I. THIS CASE SHOULD NOT BE DISMISSED BECAUSE THERE IS AN ACTUAL CONTROVERSY AND BECAUSE EXERCISING SUBJECT MATTER JURISDICTION IS APPROPRIATE.

A declaratory judgment action may be brought to resolve an "actual controversy" between "interested" parties. 28 U.S.C. § 2201. So long as there is such a controversy, a court may exercise subject matter jurisdiction over a declaratory judgment action.

In the context of claims for declarations of patent rights and relationships, such as claims 1 through 4 of Genentech's Complaint for Declaratory Judgment of Invalidity and Unenforceability of U.S. Patent No. 6,455,275 and Breach of Contract (the "Complaint"),[6] an actual controversy exists if (1) there is a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) there is present activity that could constitute infringement or there have been concrete steps taken with the intent to conduct such activity. See, e.g., SVG Lithography Sys., Inc. v. Ultratech Stepper, Inc., C.A. No. 01-11766-MLW, 2004 WL 1948742, at *2 (D. Mass. Mar. 6, 2004); Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1058 (Fed. Cir. 1995); Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 736 (Fed. Cir. 1988). Whether "reasonable apprehension" and "present activity" or "concrete steps taken with the intent to conduct such activity" are present is determined on a case by case basis upon consideration of the totality of the circumstances – "generally applicable rules are few." Super Sack, 57 F.3d at 1058; see also Aetna Life

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substantially identical to, a claim of the '275 patent as it currently reads."); id. Ex. A (September 17, 2004 Letter from David I. Gindler) ¶ 5(b) ("The Covenant does not extend to any claim in any patent that may issue in the future based on the '159 application, without exception.").)

[6] Columbia does not contend that this Court lacks subject matter jurisdiction over claim 5 of the Complaint. (Mem. at 7-8 & App. 1.)

Ins. Co. v. Haworth, 300 U.S. 227, 239-41 (1937); Arrowhead, 846 F.2d at 736; Int'l Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc., 787 F.2d 572, 575 (Fed. Cir. 1986). The circumstances present here demonstrate an actual controversy – and hence subject matter jurisdiction – over claims 1 through 4 of the Complaint.

A. An Actual Controversy Exists

1. Genentech's presently continuing activities.

There is no doubt that Genentech is in the process of conducting potentially infringing activities that fall outside the scope of Columbia's Covenant. As noted above (see supra 5-6), Columbia has made it absolutely clear that its Covenant does not extend to (1) a DNA construct or a cotransformed cell created for the first time after September 1, 2004, unless the protein encoded by the DNA construct or cotransformed cell was on sale by the plaintiffs on or before September 1, 2004; (2) methods of using such DNA constructs or cotransformed cells; and (3) proteins produced using such DNA constructs or cotransformed cells. (Cov. at 1; Joint Report (Doc. No. 98), Ex. A (September 17, 2004 Letter from David I. Gindler) ¶¶ 4(a)-4(c).) But the very nature of Genentech's business requires it to continue – and Genentech has continued – to pursue the creation of just such DNA constructs and cotransformed cells, the use of just those methods, and the production of just those proteins, all of which may potentially infringe the '275 Patent.

Genentech performs research and development specifically directed to the discovery, manufacture, and sale of products that potentially infringe the '275 Patent. Genentech scientists routinely use recombinant DNA technology, including methods, DNA constructs, and cotransformed cells that potentially infringe the '275 Patent, in an effort to further Genentech's principal business objective – to discover, synthesize, study,

and sell the next generation of therapeutic compounds. (Snedecor Decl. ¶¶ 4-5; see, e.g., www.gene.com (stating that "recombinant DNA technology, the task of cutting DNA from one organism and pasting it into a new organism that reproduces to make proteins of potential therapeutic value, is the technology at the foundation of biotechnology and Genentech" and that "information on specific genes and their related proteins has always been at the core of Genentech's search for novel drug targets").)

As a result, Genentech has taken and is continuing to take numerous and significant concrete steps toward conducting activities that potentially infringe the '275 Patent. For example, Genentech allocated funds for the purchase and development of the facilities and tools needed to grow and harvest cells for the purpose of conducting potentially infringing activity, and spent $722 million in 2003 and more than $400 million to date in 2004 to conduct research aimed specifically at discovering, manufacturing, and selling potentially infringing pharmaceutical products (see Snedecor Decl. ¶¶ 2-4, Ex. A at 9, & Ex. B).[7] See Arrowhead, 846 F.2d at 739 (finding a justiciable controversy because "we are not dealing here with a mere plan or wish to practice the process[es]" at issue); Glaxo Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1571 (Fed. Cir. 1997) (finding an actual controversy where a pharmaceutical company alleged that it intended to market a potentially infringing drug); Super Prods. Corp. v. DP Way Corp., 546 F.2d 748, 753 (7th Cir. 1976) (finding an actual controversy because "[n]ot only do the facts disclose an apparent ability and a definite intention on the part of

[7] It is important to note that this is not a case in which the "concrete steps" consist of new drug compounds in Genentech's "pipeline" that will not potentially infringe the '275 Patent until those products are sold in the future. The potentially infringing activity here is much more immediate: it is the actual conduct of Genentech's day-to-day business – the research efforts that lead to the synthesis of compounds that can be studied for possible therapeutic effects – that potentially infringe the '275 Patent.

plaintiff to manufacture and sell a product similar to the one described in defendant's patent, but they establish the existence of a business enterprise specifically directed to the manufacture and sale of a potentially infringing product") (cited with approval in Arrowhead, 846 F.2d at 738); Welch v. Grindle, 251 F.2d 671 (9th Cir. 1957) (holding that a justiciable controversy existed where the plaintiff had not actually manufactured, used, or sold infringing products but had alleged that he had organized a corporation with adequate financial resources and business plans to produce infringing products); see also Int'l Med. Prosthetics, 787 F.2d at 575. Accordingly, Genentech's continuing activities will potentially infringe the '275 Patent and form the basis of an actual controversy over which subject matter jurisdiction exists.

This Court's decision in SVG does not compel a different conclusion. In SVG, this Court found that the declaratory judgment plaintiff "failed to establish that it actually intends to make, use or sell products containing the component in the future," SVG, 2004 WL 1948742, at *4, noting that a "current desire and amorphous plans" to produce future potentially infringing products do not constitute "sufficiently concrete steps to support an Article III case or controversy." Id. Here, however, Genentech has shown the requisite concrete steps to support a finding of subject matter jurisdiction. (See supra 8-9.) Hence, a finding of subject matter jurisdiction would be consistent with this Court's decision in SVG.[8]

[8] A finding of subject matter jurisdiction here is also consistent with the Super Sack and Amana cases on which Columbia relies (Mem. at 5-7). Unlike Genentech, the declaratory judgment plaintiffs in Super Sack and Amana had not taken concrete steps toward conducting potentially infringing activity. Super Sack, 57 F.3d at 1059-60 (noting that the plaintiff "never contended that it has already taken meaningful preparatory steps toward an infringing activity by planning to make a new product that

2. The Covenant does not address Genentech's previous royalty payments.

Genentech has made royalty payments of more than $100,000 related to the '275 Patent. Because the '275 Patent is invalid and unenforceable, Genentech is entitled to recover those payments from Columbia. See, e.g., Warner-Jenkinson Co. v. Allied Chem. Corp., 567 F.2d 184, 188 (2d Cir. 1977) ("Once the plaintiffs have proved patent invalidity, they would become entitled to withhold future royalties and to receive restitution of royalties paid pendente lite (with interest)."). The recovery of past royalty payments is not addressed by Columbia's Covenant, and therefore Genentech's right to recover those payments – an issue that requires a determination of the enforceability of the '275 Patent – gives rise to another actual controversy that creates subject matter jurisdiction here.

B. Existing Subject Matter Jurisdiction Should Be Exercised Here.

As this Court recognized in SVG, where there is an actual controversy, the exercise of subject matter jurisdiction "rests within the sound discretion of the district court." SVG, 2004 WL 1948742, at *5. Exercising subject matter jurisdiction is especially appropriate in this case.

First, it is clear that, if subject matter jurisdiction were not exercised, Genentech would face the same "uncertainty of litigation" that impacted its business to such an extent that Genentech was prompted to seek declaratory judgment relief in the first place. Id. Although the Covenant resolves the uncertainty surrounding some of Genentech's current products, substantial uncertainty remains. Columbia is not relinquishing its

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may later be said to infringe"); Amana Refrigeration, Inc. v. Quadlux, Inc., 172 F.3d 852, 855 (Fed. Cir. 1999). Thus, Columbia's reliance on these cases is unavailing.

claims under the '275 Patent relating to potentially infringing activities that have been supported by substantial past and continuing investments. Moreover, there remains uncertainty regarding the research and development routinely conducted for the specific purpose of continuing to create potentially infringing DNA constructs, transformed cells, and pharmaceutical products.

Second, exercising jurisdiction here serves to further the policies underlying the Declaratory Judgment Act and the patent laws "by enabling a test of the validity and infringement of patents that are possibly being used only as what Learned Hand called 'scarecrows.'" Arrowhead, 846 F.2d at 735 n.4 (citing Bresnick v. United States Vitamin Corp., 139 F.2d 239, 242 (2d Cir. 1943) (L. Hand)); see also Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha, 57 F.3d 1051, 1053 (Fed. Cir. 1995) ("[T]he purpose of the Declaratory Judgment Act is to enable those threatened to remove such a cloud on their commercial activity, instead of being obliged to await the convenience of the threatening party."). The long list of delay tactics – including the pending motion to dismiss – that Columbia has employed in an effort to postpone the resolution of the dispute over the validity of the '275 Patent evidences Columbia's intent to use the unenforceable '275 Patent merely as a "scarecrow." Columbia should not be permitted to reap economic gain from an unlawful extended monopoly while frustrating "the important public interest in permitting full and free competition in the use of ideas that are in reality a part of the public domain." Lear, Inc. v. Adkins, 395 U.S. 653, 670 (1969). Under such circumstances, exercising subject matter jurisdiction over claims 1 through 4 of the Complaint is particularly appropriate. See, e.g., Wembley, Inc. v. Superba Cravats, Inc., 315 F.2d 87 (2d Cir. 1963) (noting that the declaratory remedy

"should be construed with liberality in the patent field" because without the availability of declaratory relief, patentees unfairly gain manifold advantages by the device of threatening alleged infringers with lawsuits which could always be dismissed without the possibility of such persons taking steps to ascertain the validity of the patentee's claims).

II. GENENTECH'S BREACH OF CONTRACT CLAIM SHOULD NOT BE REMANDED TO THE NORTHERN DISTRICT OF CALIFORNIA.

If this Court finds and exercises subject matter jurisdiction over claims 1 through 4 of the Complaint – as it should – then Columbia's arguments in favor of recommending the remand of claim 5 of the Complaint are moot. But, even if this Court were to dismiss claims 1 through 4 of the Complaint for lack of subject matter jurisdiction, claim 5 should proceed before this Court.

Contrary to Columbia's assertions (Mem. at 8-9),[9] recommending the remand of Genentech's breach of contract claim to the Joint Panel on Multidistrict Litigation would not "further the just and efficient" resolution of that claim. In re Adelphia Communications Corp. Sec. & Derivative Litig., 237 F. Supp. 2d 1381, 1382 (JPML 2002). The balance of efficiencies here counsel in favor of allowing Genentech's breach of contract claim to proceed before this Court.

The breach of contract claim asserted by Genentech requires a determination as to the validity of the '275 Patent – an issue that is quickly approaching resolution here. Whether Columbia's unilateral termination of the License Agreement, which was based on the failure of Genentech to pay royalties related to the '275 Patent, and whether

[9] Columbia's request for remand appears to be related to Columbia's desire to delay any adjudication of the validity of the '275 Patent. Only such a motive could explain Columbia's motions to transfer, its initiation of MDL proceedings, and its present request for remand.

Genentech can recover the royalties it has paid with respect to the '275 Patent would be analyzed most efficiently by this Court.

Moreover, Columbia's proposal that Genentech's breach of contract claim be remanded to the Northern District of California and that Johnson and Johnson's breach of contract claim be remanded to the Southern District of New York creates the potential for inconsistent rulings on issues relating to the validity of the '275 Patent. Accordingly, claim 5 of the Complaint should proceed before this Court on the schedule set in this Court's June 23, 2004 Order.[10]

III. JURISDICTION EXISTS OVER GENENTECH'S REQUEST FOR ATTORNEY FEES PURSUANT TO 35 U.S.C. § 285.

Even if the Court finds no subject matter jurisdiction over claims 1 through 4 of the Complaint and recommends remand, this Court has jurisdiction to consider Genentech's request for attorney fees under 35 U.S.C. § 285 (Complaint ¶¶ 51, 57 & 65). Jurisdiction over a request for attorney fees pursuant to 35 U.S.C. § 285 survives both the dismissal of the underlying claims for lack of subject matter jurisdiction, see H.R. Technologies, Inc. v. Astechnologies, Inc., 275 F.3d 1378, 1386 (Fed. Cir. 2002), and the voluntary dismissal of claims related to the validity and enforceability of a patent, see, e.g., Cambridge Products, Ltd. v. Penn Nutrients, Inc., 131 F.R.D. 464, 467 (E.D. Penn. 1990); Bioxy, Inc. v. Birko Corp., 935 F. Supp. 737, 744 (E.D.N.C. 1996); W.L. Gore & Assocs., Inc. v. Oak Materials Group, Inc., 424 F. Supp. 700, 702 (D. Del. 1976).

[10] If this Court is not inclined to proceed with Genentech's breach of contract claim pursuant to the schedule currently in place, that claim should alternatively be stayed pending the conclusion of the reexamination and reissue proceedings being conducted in the United States Patent and Trademark Office with regard to the '275 Patent. This alternative would serve the interests of just and efficient adjudication in the event that the results of the reexamination and reissue proceedings require Genentech to file claims similar to those currently close to resolution before this Court.

Accordingly, even if all or part of Columbia's motion to dismiss claims 1 through 4 and to remand claim 5 is granted, Genentech respectfully requests that this Court decide the merits of Genentech's request for attorney fees pursuant to 35 U.S.C. § 285.

Conclusion

For the reasons set forth above, Columbia University's motion to dismiss claims 1 through 4 of Genentech Inc.'s Complaint and to recommend remand of claim 5 of Genentech Inc.'s Complaint should be denied.

DATED: September 22, 2004

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